



K964382
April 15, 1997

Subject: 510(k) Summary of Safety and Effectiveness

Product: Gibeck Humid-Vent® Filter Compact
Angled/Humid-Vent® Filter Compact Straight

Summary:

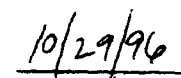
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Humid-Vent Filter Compact Angled/Humid-Vent Filter Compact Straight are heat and moisture exchangers as described in 21 CFR 868.5375. These products are substantially equivalent to the Gibeck Humid-Vent Filter heat and moisture exchanger.

The Humid-Vent Filter Compact Angled/Humid-Vent Filter Compact Straight are similar in design, materials and function to the Humid-Vent Filter with reduced size, dead space and lighter weight. The reduced dead space of the Humid-Vent Filter Compact Angled/Humid-Vent Filter Compact Straight allows for a tidal volume range of 150-1000 ml.

The principal difference between the Humid-Vent Filter Compact Angled/Humid-Vent Filter Compact Straight and the Humid-Vent Filter is the size of the device. This change is not considered to be critical to the intended therapeutic, diagnostic, prosthetic or surgical use of the device nor should this change significantly affect the safety or effectiveness of the device when used as labeled.


Submitter/Contact Person


Date

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